SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING MARCH 3, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on March 3, 1999, at 11 a.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency's (EPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. A list of parking lot issues and frequently asked questions is given in Attachment C. Attachment D presents the QS Committee's approach to handling comments, comment acknowledgment form letter, commenter template, and guiding principles for reviewing comments and the standard. Changes to the language in Chapter 5 proposed at this teleconference are reflected in Chapter 5, Revision 10.2 of the standard. *The purpose of the meeting was to review action items from previous meetings and discuss comments received at the NELAC IVi* meetings.

REVIEW OF ACTION ITEMS FROM THE PREVIOUS TELECONFERENCE

The committee reviewed the actions items from the previous teleconference. Any items not addressed are carried over as action items in Attachment A.

Language will be added to the introductory paragraph in Appendix C to make it clear that the Initial Demonstration of Capability (IDOC) requirements are not intended to be a test of analytical capabilities in a "real world" matrix.

The committee discussed the requirements for matrix spikes in Section D1.1 because comments had been received that matrix spikes are of little value and the requirements are not reasonable. A comment was made that matrix spikes are essential for environmental analyses. In addition, they are an important component in trying to link the requirements of the standard to data quality objectives and they help the data user understand the quality of the data. Furthermore, the current requirements are minimal. The committee decided to leave the requirement unchanged.

Mr. Slayton, Mr Chuck Glowacki, and Mr. Scott Siders will participate in the March 9 teleconference with ELAB to answer questions they may have about the current standard.

The committee continues to receive comments from individual EPA program offices. The committee would like to see consensus EPA comments come through the Environmental Monitoring Management Council (EMMC). The comment was made that EMMC may not be able to develop a consensus set of EPA comments due to the technical differences between the EPA programs. However, it was pointed out that Chapter 5 is a high level "umbrella document" and that specific quality control (QC) requirements (for methods specified in regulations) could be included in the Code of Federal Regulations (CFR) requirements, analytical methods, or that specific performance criteria could be established for Performance Based Measurement Systems (PBMS).

DISCUSSION OF ISSUES RAISED AT NELAC IVI

Section 5.6.2.b and c: The language will be revised so that item b will address initial demonstration and item c will address ongoing proficiency.

Section 5.10.2.1: The question was raised as to whether a sensitivity check is needed as part of requirements for IDOC. The committee felt that this would be redundant with the requirements for establishing detection limits.

Appendix C: IDOC will be revisited to address methods that do not lend themselves to spiking, to separate independent analyst proficiency from laboratory capability, and to address the work cell concept.

Section 5.9.4.1.f: This section will be divided into two sections, f and g. Section f will cover autoclave use where it necessary to only measure temperature and g will cover uses where it is necessary to measure temperature and pressure.

Section 5.9.4.e: It may be necessary to add language that specifically covers checks for disposable devices.

Section 5.12.3.1.n: This section will be replaced with International Standards Organization (ISO) Guide 25 language.

Section 5.12.4: The title will be changed to *Legal/Evidentiary Custody* from *Legal or Evidentiary* to make it more clear that legal and evidentiary are not two different types of custody, but are synonymous.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
MARCH 3, 1999

Item No.	Action Item	Date to be Completed
1.	Mr. Cross to review the table of contents to Chapter 5.	March 5, 1999
2.	Mr. Slayton to get new contact information for Ms. Bruch	Prior to next teleconference
3.	Mr. Slayton to finalize the new Q&A list, which will be reviewed at the next QS Committee teleconference.	Prior to next teleconference
4.	Mr. Glowacki to provided an updated definition of the term *blank.*	
5.	Mr. Slayton to make changes to Chapter 5 agreed upon during this teleconference.	
6.	Mr. Frederici and Mr. Porterfield to draft introductory paragraphs for the new appendix containing a list of records and procedures required by Chapter 5.	
7.	Mr Frederici and Mr. Siders to review the references they submitted for calibration and detection. Also, the Committee should review the references Mr. Slayton distributed.	
8.	The QS Committee will revisit, at the next teleconference, the issue of the *work cell* in 5.6.2	
9.	Mr. Glowacki to lead a discussion, at an upcoming teleconference, concerning the comments and revisions to the air testing section of Chapter.	
10.	QS Committee owes a response to comments received from Ms. Karopilak and Mr. Miller of the New Jersey Department of Environmental Protection. Also, comments received from Mr. Hall of Quanterra will divided among the committee participants to prepare draft responses.	
11.	An agenda item for the next teleconference is to discuss election of new committee participants, which will occur at the NELAC V. New terms start after the close of the NELAC V session.	

Attachment A (Cont.)

Item No.	Action Item	Date to be Completed
12.	Mr. Slayton to check with Ms. Jeanne Mourrain about the last date to submit a version of Chapter 5 for publication for NELAC V.	
13.	Mr. Slayton to search Chapter 5 for occurrences of language regarding requirements in the standard that differ from requirements in an analytical method. This language will be modified to state that where it is unclear which requirements are more stringent, the mandated must be followed.	

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
MARCH 3, 1999

Name	Affiliation	Phone/Fax/E-mail
Slayton, Joseph Chair	U.S. EPA/Region 3	T: 410-305-2653 F: 410-305-3095 E: slayton.joe@epamail.epa.gov
Bruch, Mary (Absent)	Mary Bruch Micro Reg. Inc.	T: 703-589-1514 F: 703-779-0267 E: --- none ---
Frederici, Raymond	Recra Labnet	T: 708-534-5200 F: 708-534-5211 E: frederir@recra.com
Glowacki, Clifford	Ashland Chemical Co.	T: 614-790-3482 F: 614-790-4294 E: cglowacki@ashland.com
Labie, Sylvia	Florida Dept. of Env. Prot.	T: 904-488-2796 F: 904-922-4614 E: labie_s@dep.state.fl.us
Mendenhall, David	Utah Dept of Health	T: 801-584-8470 F: 801-584-8501 E: dmendenh@doh.state.ut.us
Meyers, Sheila (Absent)	TNRCC	T: 512-239-0425 F: 512-239-6307 E: smeyers@.tnrcc.state.tx.us
Nielsen, Jeffrey	City of Tallahassee, Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
Porterfield, Donivan	Los Alamos National Lab., AQ & CIM	T: 505-667-4710 F: 505-665-4737 E: dporterfield@lanl.gov
Siders, Scott	Illinois EPA	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
Siegelman, Fred (Absent)	USEPA/ORD/QAD	T: 202-564-5173 F: 202-565-2441 E: siegelman.frederic@epamail.epa.gov
Cross, Mike (Contractor Support)	Research Triangle Inst.	T: 202-728-2045 F: 202-728-2095 E: myc@rti.org

Attachment C

PARKING LOT ITEMS/ISSUES AND FREQUENTLY ASKED QUESTIONS
QUALITY SYSTEMS COMMITTEE
MARCH 3, 1999

Items/issues will remain in the Parking Lot until they are completed.

1. Air Appendix

Need to review and finalize

2. Proposed New Appendix

Appendix for listing of required records and procedures. Need introduction and (all pulled into one table). Need to reach consensus on the table and the suggested introduction provided by D. Porterfield and Ray Frederici (leads).

3. Initial Demonstration of Capability:

Need to address an IDOC for tests for which you can not spike. Also, does IDOC need to be universal and address all medias? Donivan Porterfield is lead.

4. Definitions/Glossary

Changes necessary to be consistent with Program Policy and Structure proposal. QS Committee will review definitions/glossary at interim meeting.

5. Q & A are due to Outreach Committee.

6. Review comments from NELAC IVi.

7. Review comments received since NELAC IVi.

8. Need to vote in two new members to QS committee.

9. Final QS chapter due to Board Due April 30th

Some Frequently Asked Questions Concerning NELAC QS (Chapter 5)

1. Question: If a mandated method (required by EPA or State Authority) is less stringent than the QS standards what do I follow?

Answer: The most restrictive/demanding.

2. Question: Do the QS standards require the use of any specific method?

Answer: No

3. Question: Do the QS standards allow for the use of the PBMS approach?

Answer: Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

4. Question: Do the QS standards apply to small laboratories?

Answer: Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented SOPs and QC procedures) more then upon the size of the laboratory.

5. Question: If my laboratory is measuring high level concentrations and is set-up (perhaps even optimized) to analyze at such levels and is only interested in whether a high level regulatory limit is exceeded, why do I have to determine a detection limit?

Answer: A detection limit is considered essential to verify (confirm and document) that the laboratory is actually able to detect and measure at the regulatory or decision limit. Detection limit determinations are also considered an important consideration with regard to the quantitation range selection particularly with regard to the choice of the concentration of the lowest calibration standard. Changes to the standard will be proposed at the January 1999 Interim Meeting, which no longer specify that the MDL (40 CFR Part 136) procedure be employed, unless it is mandated by the test method or applicable regulation. In the proposed revision, the term “detection limit” may not be the lowest concentration level attainable by a given analytical method, but rather that it is a concentration that is actually measurable (and verified) using the procedures, e.g., equipment, analytical method, routinely employed for sample analyses (could be relatively high concentration). The detection level should be appropriate or relevant for the intended use of the data. In some cases this will of necessity be the lowest concentration level attainable, e.g., low level drinking water or wastewater permit limits.

Attachment D

ACKNOWLEDGEMENT LETTER, REVIEW GUIDELINES, and COMMENTER TEMPLATE
Quality Systems Committee
March 3, 1999

Date:

Dear :

On behalf of the Quality Systems Committee, thank you for your comments on the Chapter 5 standards of the National Environmental Laboratory Accreditation Conference (NELAC). The standards are routinely reviewed and updated. Continual improvement of the standards is the focal point of NELAC process. We encourage your continued written input as well as your attendance at the NELAC interim meeting and yearly conference. Also, our committee routinely schedules 1-2 open forum meetings during each calender year.

Our committee requests that all comments be supplied in electronic format (WordPerfect if possible) and that handwritten, hardcopy and the use of color fonts be avoided. Comments are considered by the QS committee on a first come basis. We have placed a template (table) for comments on the NELAC Web page, which we hope will ensure that the processes is efficient. With this process we hope that emphasis can be placed on consideration of the comments so that the available time is not spent in the mechanics of exchanging information (US Mail and re-typing comments). Routinely, each set of comments is assigned a QS leader who will complete the comment table including suggested language for any proposed changes to the NELAC standards. The Leader will guide a discussion of the comments during routine committee meetings. The minutes of the meeting (posted on the web site) will capture the information in the completed table from committee discussions, thoughts/rationale and present the final decisions.

Again, thank you for taking the time and effort to improve the NELAC Quality System standards.

Sincerely,

Joseph Slayton, Chair
Quality Systems Committee

QS Approach: Comments Received and QS Response:

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following table:

GUIDING PRINCIPLES/REVIEW CRITERIA

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Comment ID #: , Source of Comments (Name): QS Lead on Response (Name):			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled In by Commentor)	**COMMENTwith Rationale to QS (To Be Filled in my Commentor)** **New Wording for Standard (To Be Filled In by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**